



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/484,879	01/18/00	ALVAREZ	

020583  
PENNIE AND EDMONDS  
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NEW YORK NY 10036-2711

HM12/1023

EXAMINER	
CELSA, B	PAPER NUMBER
ART UNIT	

1627  
DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/484,879

Applicant(s)

Alvarez, V.L.

Examiner

Bennett Celsa

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Apr 24, 2001
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4, 6, 8, 10, 15-17, 19, 21, 23, 24, 26, 27, 30, and 35-46 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 2-4, 6, 8, 10, 15-17, 19, 21, 23, 24, 26, 27, 30, and are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## DETAILED ACTION

### *Status of the Claims*

Claims 2-4, 6, 8, 10, 15-17, 19, 21, 23, 24, 26, 27, 30 and 35-46..

### *Withdrawal of the Prior Office action and Institution of Restriction/Election*

The present application has been transferred from Examiner Wessendorf to Examiner Celsa.

In light of the newly amended claims and in light of the nature of the presently claimed invention, restriction and election of species is deemed necessary, more specifically in view of:

- a. the presence of independent and/or distinct inventions;
  - b. in order to obtain a complete search; and/or
  - c. in order to permit the Examiner the opportunity to properly address the individual issues unique to each of the below invention (s),
- all of which will serve to expedite the prosecution of the present application as well as any future application(s) resulting therefrom.

*The Examiner sincerely regrets any inconvenience that results to applicant and applicant's representative(s).*

The prior office action is withdrawn, without prejudice to any of the rejection(s) contained therein. The next office action on the merits will be a non-final office action which will afford applicant a complete opportunity to address (if not already addressed in applicant's response of 4/24/2001) any issues (objections/rejection) re-raised in the next office action as well as any newly raised issues.

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It is first noted that claim 26 is improperly dependent upon a cancelled base claim (e.g. claim 1) and thus is not present in any of the groups below. Upon applicant amendment of claim 26, the placement of the amended claim 26 (if necessary) in the below groups will be reevaluated.

It is also noted that it is the PTO policy to view product-by-process claims as product claims; and these claims have been grouped accordingly, below.

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 2-4, 6, 8, 10, 27, 30, 36 and 45, drawn to an antibody-like molecule comprising a peptide and compositions thereof, classified in class 530, subclass 387.1.
  - II. Claims 15-17, 19, 21 and 46, drawn to an immunological screening method of a combinatorial library(ies), classified in class 435, subclass 7.1.
  - III. Claims 23-24, drawn to a method of screening a sample for analyte binding, classified in class 436, subclass 501+.
  - IV. Claim 13, drawn to specific peptides of seq.id 1-5 "or a binding portion thereof", classified in class 530, subclass 324 and additional subclasses dependent upon the length of the "binding portion".
  - V. Claim 33, drawn to receptor-like molecule comprising a peptide or "binding portion thereof", classified in class 530, subclass 388.22.

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- VI. Claim 35, drawn to an in vivo radioimmunoassay involving tumor antigens, classified in class 436, subclass 545.
- ~~VII.~~ Claim ~~37~~, drawn to a (prostate carcinoma cell antigen binding) peptide comprising seq. Id. 23 and 24, classified in class 530, subclass 389.7.
- ~~VIII.~~ Claims ~~38~~ and ~~41~~, drawn to a molecule comprising a peptide of seq id 26-56 and composition thereof, classified in class 514, subclass 2+.
- ~~IX.~~ Claim ~~39~~ and ~~42~~, drawn to a molecule comprising a peptide of seq. Id 57-76, classified in class 514, subclass 2+.
- X. Claim 40, drawn to a molecule which binds a peptide of seq. Id 9 'or a portion thereof', classified in various class/subclasses depending upon the composition of the "molecule".
- XI Claims 43 and 44 drawn to a (polymorphic epithelian mucin binding) molecule comprising the generic of seq. Id 88 , classified in class 530, subclass 300.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I, IV, V and VII-XI are individually drawn to independent and/or distinct compounds which comprise different peptides of different length and/or amino acid composition which have different physicochemical, biological characteristics are capable of separate manufacture and/or use and which require different and separately burdensome manual and/or computer sequence, classification and bibliographic searches.

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4. Inventions II, III and VI are individually drawn to independent and/or distinct methods in accordance with their different method objectives, method steps, use of different reagents and/or which require different and separately burdensome manual and/or computer, classification and bibliographic searches.
5. Inventions I and (III or VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product as in Group III (screening an analyte) or Group VI (in vivo radioimmunoassay of tumor antigens).
6. Inventions II and I are related as process of making (or identifying) and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made (or identified) by another and materially different process screening combinatorial libraries for single chain antibodies (e.g. see US 6015561 at col. 4); or the process as claimed can be used to make other and materially different products such as peptide receptor mimics (vs. peptide antibody mimics).

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7. Inventions (I, IV, V, VII, VIII, IX, X or XI) as compared to Inventions (II, III or VI) are drawn to independent and/or patentably distinct inventions since Inventions (I, IV, V, VII, VIII, IX, X or XI) as compared to the Inventions (II, III or VI) are drawn to different statutory class of inventions, require different patentable issues (e.g. under 35 USC 101, 112, 102 and 103); and require different and separately burdensome manual and computer bibliographic and/or classification searches. Additionally, the compounds of Inventions (I, IV, V, VII, VIII, IX, X or XI) have different modes of operation and/or different functions and/or different effects as compared to the methods of Inventions (II, III or VI).
8. Because these inventions are distinct for the reasons given above and
- have acquired a separate status in the art as shown by their different classification; and/or
  - required different and separately burdensome manual and/or computer searches; and/or
  - because these inventions have acquired a separate status in the art because of their recognized divergent subject matter,
- restriction for examination purposes as indicated is proper.

**ELECTION OF SPECIES** (For Groups IV, V, VIII or IX)

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups IV, VIII or IX, independent and/or distinct PEPTIDES ("or binding portions thereof for gp IV) of different length and/or amino acid composition which have different physicochemical, biological characteristics are capable of separate manufacture and/or use and

which require different and separately burdensome manual and/or computer sequence, classification and bibliographic searches.

For Group V, a molecule comprising a peptide in which may potentially result in a molecule of different composition and/or different physicochemical, biological characteristics are capable of separate manufacture and/or use and which require different and separately burdensome manual and/or computer sequence, classification and bibliographic searches depending upon the nature of the RECEPTOR MOLECULE.

Applicant is required under 35 U.S.C. 121 to elect:

- A. a single disclosed species of **peptide** (or binding portion thereof) for Groups IV, VIII or IX or
  - B. a specific **receptor molecule** for Group V;
- for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)

October 19, 2001

BENNETT CELSA  
PRIMARY EXAMINER

